REMARKS

This is in response to the Office Action mailed March 13, 2003. Claims 1, 26, 27, 32, and 50-52 have been amended. Claims 56-58 have been added. Claims 1-58 are currently pending and at issue.

Claims 1, 26, 27, and 52 have been amended to recite that the "pharmaceutical composition is free of valproic acid." Support for this amendment is found in the specification at, for example, page 4, lines 10-14. See also page 5, line 19, describing a "solid valproic acid derivative."

Claims 1, 26, and 27 have also been amended to add "when tested" to clarify that the storage conditions are part of a test. Support for this amendment can be found at page 7, lines 14-17, and specifically on line 16.

Claim 7 has been amended to be directed to direct compression. Support for this amendment is found in the specification at, for example, page 9, lines 4-6. See also page 21, lines 17-18.

Claim 32 has been amended to correct an obvious typographical error.

Claims 50 and 51 have been amended to further clarify the presently claimed invention.

Claim 52 has been amended to replace the term "carrier" with --carbomer--, an obvious error. Support for this amendment is found in the specification at, for example, page 7, line 22 to page 8, line 19. Moreover, this amendment provides antecedent basis for the term "the carbomer" as recited in claim 52.

New claims 56 and 57 result from the combination of the subject matter of: (i) claims 1, 3, and 5; and (ii) claims 1, 3, 5, and 7. Support for these claims is also found in the specification at, for example, page 8, lines 16-19; page 9, lines 4-6; as well as in the original claims.

New claim 58 depends from claim 27 and is directed to direct compression. Support for this claim is the same as that cited above with respect to claim 7.

No new matter has been added. Reconsideration of the application is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-55 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Aubert et al. (U.S. Patent No. 5,185,159) ("Aubert") in view of Barry et al. (U.S. Patent No. 5,055,306) ("Barry"). The Examiner cites Aubert as disclosing a pharmaceutical composition based on valproic acid and containing sodium valproate, calcium silicate, binders, wetting solvents, absorbent products, and lubricants. According to the Examiner, Aubert's calcium silicate represents a non-hygroscopic additive, Aubert's water or isopropyl alcohol represent non-polymeric carriers, and Aubert's binders and lubricants represent excipients. Barry is cited by the Examiner as disclosing a sustained-release formulation comprising a pharmacologically active substance (such as sodium valproate), one or more excipients (such as carbomer), and a coating covering the core. According to the

Examiner, it would have been obvious for a person of skill in the art to have used the carbomer disclosed in Barry in combination with the Aubert composition.

The rejection is respectfully traversed, and reconsideration is requested.

Neither Aubert nor Barry teach or suggest the exclusion of valproic acid from the composition. In contrast, Aubert requires the incorporation of free valproic acid into its process and composition. On the other hand, each of the independent claims (i.e., claims 1, 26, 27, and 52) have been amended to specify that the "pharmaceutical composition is free of valproic acid."

The main thrust of Aubert is the combination of valproic acid and a salt thereof (Aubert: col. 1, lines 43-46). Valproic acid is a necessary ingredient in the Aubert composition (Aubert: col. 2, lines 52-54, 62-68). There is no teaching or suggestion in Aubert that would have motivated a person of ordinary skill to remove one of the two essential ingredients from the Aubert composition.

Similarly, Barry provides no disclosure that would have taught a person of ordinary skill to remove the valproic acid from the Aubert composition. Barry teaches a sustained-release formulation that could generally include any one of a vast list of pharmacologically active substances, including sodium valproate. However, Barry provides no information that would have motivated a person of ordinary skill to have specifically incorporated the sodium valproate in a composition containing this active ingredient in the absence of valproic acid, the latter feature being contrary to the teachings of Aubert. There is simply no guidance on this issue.

Accordingly, neither Aubert nor Barry nor their combination renders claims 1-58 obvious. Therefore, the rejection of claims 1-55 should be withdrawn.

Furthermore, a person of ordinary skill in the art would not have been motivated to combine these two cited references because Barry teaches away from the use of a non-hygroscopic additive. Specifically, each of the independent claims (i.e., claims 1, 26, 27, and 52) recites the inclusion of a non-hygroscopic additive, which helps to delay or prevent moisture from getting to the active ingredient (a hygroscopic salt of valproic acid) and dissolving it, turning it into a liquid (see specification: p. 7, line 18; p. 11, lines 5-7; and p. 13, lines 1-3).

In contrast, Barry teaches the use of a granulating solvent: water. Barry specifically discloses the addition of water to its formulation by stating, "The blending is conveniently performed by mixing the components together with some water to produce a slightly cohesive product" (Barry: col. 8, lines 26-45). Moreover, Example 1 in Barry discloses the addition of 2.7 L of water for the manufacturing of granules (col. 9, lines 10-20). Thus, Barry teaches away from the presently claimed invention because the incorporation of this much water in the composition would risk reaching the hygroscopic salt of valproic acid and turning it into a liquid (solution). Therefore, claims 1-58 are not obvious over Aubert in view of Barry. Furthermore, Barry does not cure the deficiency of Aubert, which requires valproic acid, and Barry is inconsistent with a composition that would shield a hygroscopic salt of valproic acid from ambient moisture or water. As a result, the rejection of claims 1-55 should be withdrawn.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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By: Dianna Goldenson
Dianna Goldenson
Reg. No. 52,949
Attorney for Applicants

Darby & Darby P.C.
Post Office Box 5257
New York, NY 10150-5257
212-527-7700